VISTA
VISTA Access
VISTA Plus

ECG holter recorders

User Manual

English

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Vista

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2. Introduction

The Vista is a miniature ambulatory ECG recorder (ECG holter). It can continuously record one, two or three channels for one (Vista Access) or several days (Vista, Vista Plus).

The Vista Plus also allows the patient to perform an audio recording of his diary during the monitoring.

The Vista Access records up to 24 hours only and cannot display the patient ECG while recording.

The entire ECG is stored on a slot-in flash memory card (Compact Flash card) and can be read directly by the HolterSoft *Ultima* software installed in the computer.

The Vista recorder weighs about 100g, including flash card and batteries. It is remarkable for its small size, its LCD display, its two buttons only, and its microphone allowing the recording of voice messages.

The Vista is connected to the patient with a single multi-lead cable connected to the ECG electrodes.

HolterSoft *Ultima*, the PC Windows® software for all Novacor holter recorders, enables you:

- To read the recordings of the Holter flash card,
- To display the results of the procedure, and if required, re-organise them, and print them as a fully customised report.

3. Guarantee

NOVACOR undertakes to deliver merchandise conforming to the technical specifications mentioned and to replace any merchandise recognised as being defective.

3.1. Specific guarantees concerning the unit

NOVACOR guarantees the Vista unit for a period of one year from the date of delivery, against any defect resulting in the unit functioning abnormally.

3.2. Specific guarantees concerning the accessories

Equipment which is not an integral part of the unit, in particular the accessories and cables, is not covered by the guarantee.

3.3. Restrictions of the guarantee

The guarantee does not apply to:

1. Units repaired or opened up outside our workshop.
2. Units damaged by negligence, by accident, or because the instructions in the user's manual have not been followed.

If necessary, contact your distributor or our maintenance service. We do not accept units which have been returned without prior agreement.

3.4. Responsibilities

NOVACOR will not, under any circumstances, be held responsible for physical or material damage of whatever nature, arising either directly or indirectly from improper use of the unit or from failure to follow the instructions in the user's manual.

Although NOVACOR manufactures products to the highest standards, it cannot guarantee or be held responsible for the validity or accuracy of the measurements made by its units.

Therefore, connection of the unit, interpretation of the ensuing clinical results and the diagnosis drawn from them, are the entire responsibility of the physician. No damage, either direct or indirect, resulting from the use of one of the units can be attributed to NOVACOR, excluding the repair of the unit within the limits of the guarantee.

3.5. Users information

All customers duly registered with NOVACOR, or where applicable with one of its distributors, will be kept informed, to the best of NOVACOR's ability, of any upgrades to the Vista as they become available.

3.6. Copyrights

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Vista, HolterSoft, and their respective logos, are registered trademarks of NOVACOR SA.

Windows is registered trademark of Microsoft Corporation.

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4. Description of the equipment

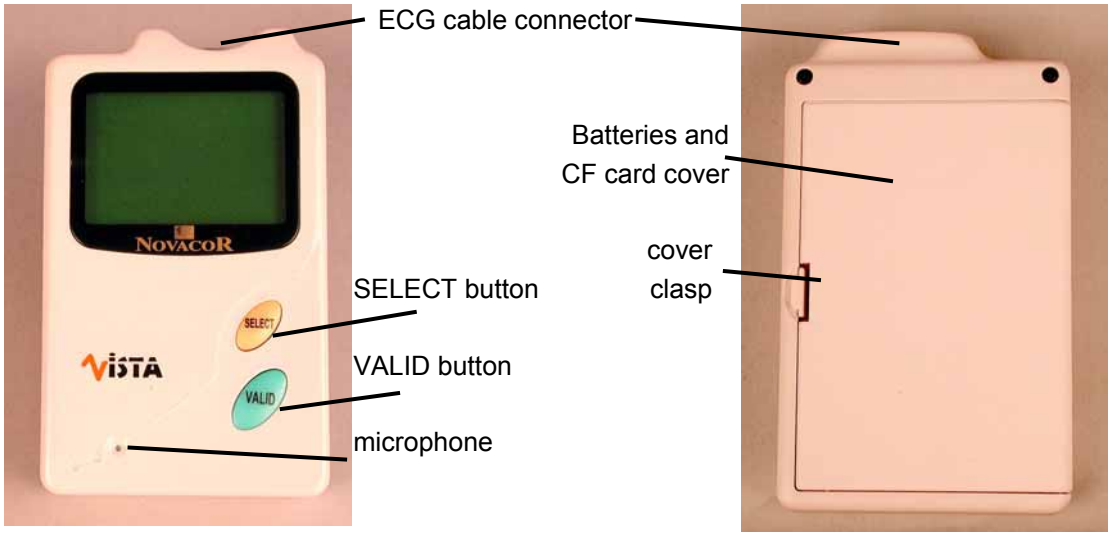
The Vista Access system includes the following standard equipment:

- Vista Access recorder and CF card,
- 5 lead ECG 'Thorax' patient cable,
- neck pouch,
- two alkaline batteries (rechargeable batteries possible) type AAA / LR03.
- HolterSoft *Ultima* software and access key, available in six languages, to be installed on a specifically configured computer, including the flash card drive, a high-resolution display, and a fast printer.

The Vista Plus recorder is also supplied with an additional pouch to install the recorder either to a belt or a shoulder strap (both supplied), and with a standard ECG cable for 2 or 3 channel recording.

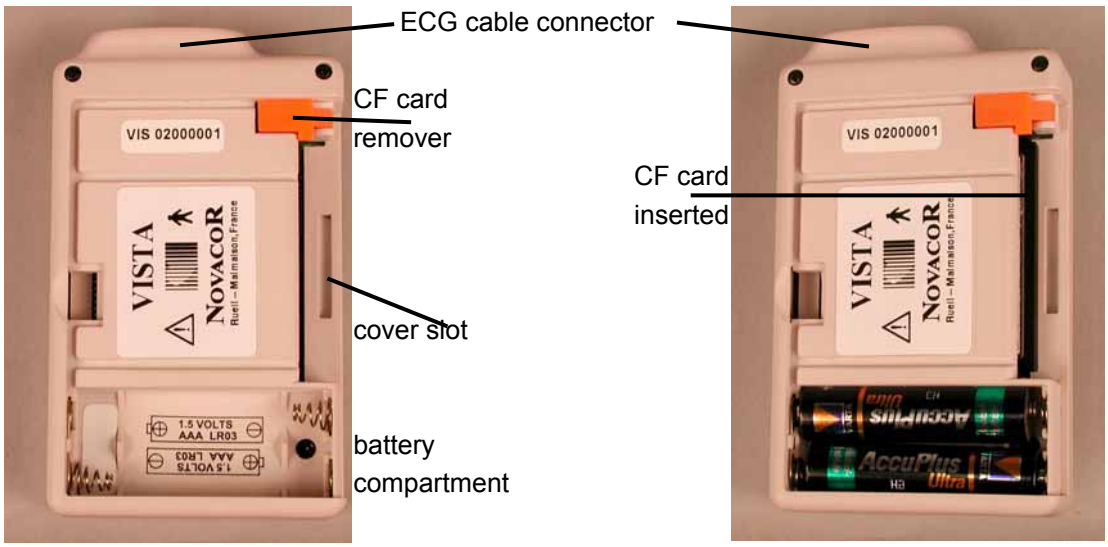
4.1. The Vista recorder

4.1.1. Device closed



front *back*

4.1.2. Device open



unit only *unit with batteries and CF card*

4.2. Cover handling

4.2.1. Opening

① Pull the strap to unlock it without moving up the cover.

② Move the cover up.

③ Remove the cover from its slot.

4.2.2. Closing

① Insert the pivoting part of the small side of the cover into the corresponding Vista slot.

② Slowly rotate down the cover, checking its correct position.

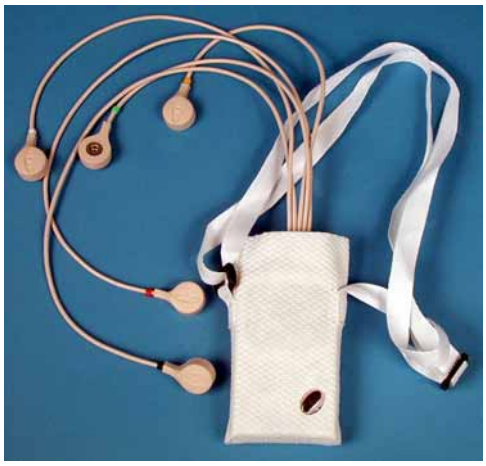
③ Close it completely by gently pressing by the lock until it clicks.

4.3. Standard accessories (all models)

Memory card
(CF card)

Thorax cable

Neck pouch



Vista and patient cable
in Neck pouch

4.4. Optional accessories

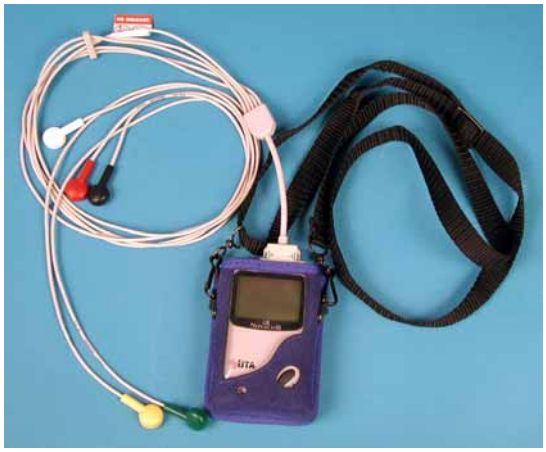
- PCMCIA PC drive – CF card adapter,
- USB CF card drive,
- 5 lead ECG cable for 2 or 3 channels, standard and long sizes,
- single size ECG cable for 2 or 3 channels for Vista Plus
- high capacity CF card for Vista Plus (256 MB or 512 MB).

*5 lead standard ECG cable (80 cm)**

5 lead long ECG cable (1,10 m)

*Pouch for belt, with shoulder strap**

*Belt**



Vista Plus, with 5 lead standard ECG cable, in its pouch with the shoulder strap.

* 5 lead standard ECG cable and pouch with belt and shoulder strap are supplied with Vista Plus recorder, and are optional for Vista Access unit.

4.5. Standard 5 wire ECG cable

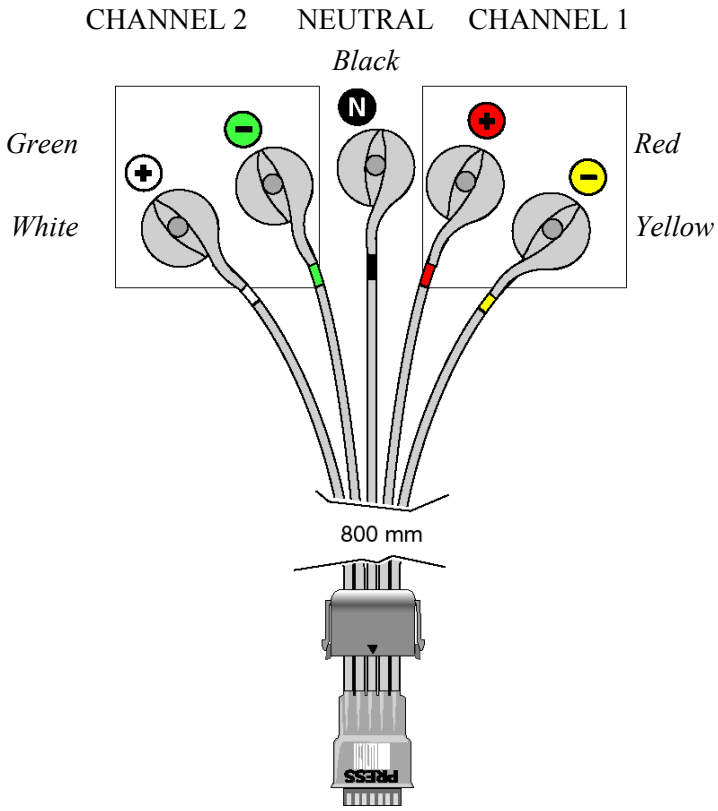
Its 80 cm length allows most patients to wear the Vista either on a belt or on a shoulder strap.

A longer 110 cm model is also available on request.

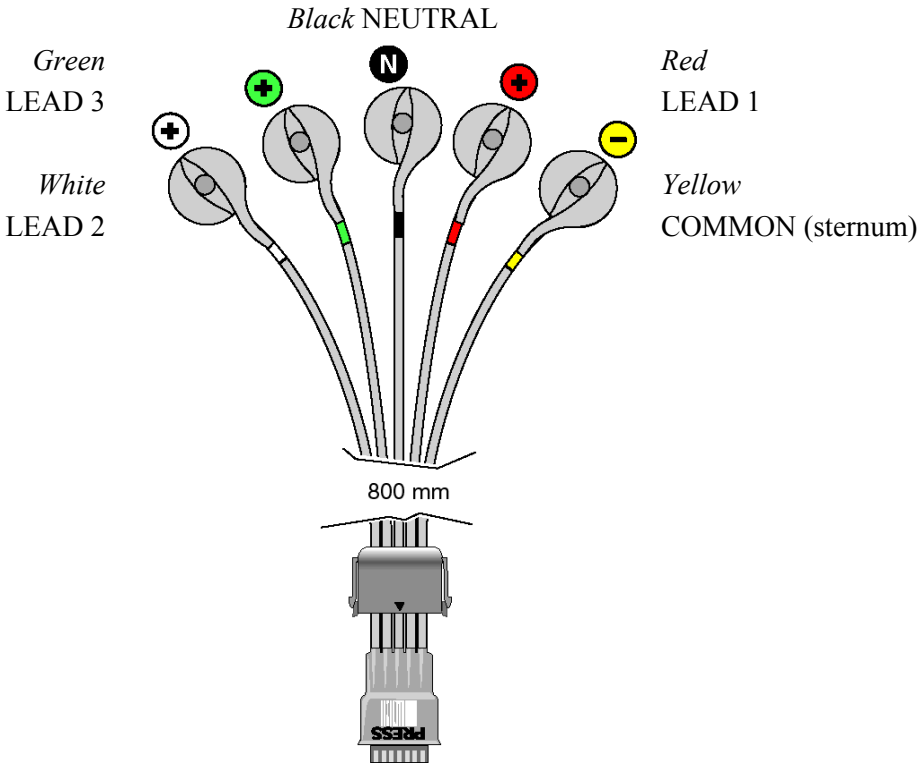
With standard 5 wire patient cable it is possible to record :

- either 2 separate bipolar leads, using RED and YELLOW tips for the 1st channel, and WHITE and GREEN tips for the 2nd one; BLACK tip being for neutral,
- or 3 bipolar leads, using YELLOW tip as a common point on the upper part of sternum, and RED, WHITE and GREEN tips respectively as the second point of channels 1, 2 and 3. BLACK tip remains neutral point.

4.5.1. Two channel recording



4.5.2. Three channel recording



4.6. 5 wire 'thorax' ECG cable

The Vista can be worn on the chest, using light pouch (neck pouch) and special small cable (thorax cable).

The 'Thorax' cable is designed for 2 channel recording only.

An adhesive patch (or, failing that, an extra ECG electrode) can be fixed on the skin and clicked to the back of the neck pouch to keep the device in place.

5. How the Vista functions

Preparation of a new monitoring is directly performed on the recorder, a computer not being required.

The Vista, thanks to its large display and its two keys only, can be easily initialised in a few seconds.

Vista recorders offer advanced features allowing:

- to record patient ID as a voice message lasting up to 20 seconds,
- to display patient ECG
  during Vista hook-up,
  or during monitoring (except Vista Access),
- and for a patient equipped with the Vista Plus, to record his diary as a voice message during the monitoring.

Download of results to the PC is performed by reading the removable memory card (CF card) on which the procedure had been recorded by the Vista.

After being read, a CF card need not be erased or programmed on the PC to be used again for a new monitoring.

5.1. The ECG Holter

The Vista fulfils users expectation with its thorough miniaturization, display capability, technical performance, and quick off-line setting.

5.1.1. The Holter recording

Two or three bipolar ECG channels are collected with a 5 lead patient cable, digitised at 200 Hz in real time, and stored on a CF card without any compression.

The CF card combines the advantages of a solid memory (digital signal, no wear and tear or distortion) with those of a cassette (light, separate from recorder). It can be read by the computer using a standard CF card drive, preferably connected to a USB port.

If the computer includes a PCMCIA card drive, a specific adaptor allows insertion of the CF card in, thus allowing previous HolterSoft users to read CF cards without any additional installation.

The recorder has a similar connector into which the CF card is inserted, for new monitoring setting and recording.

After the CF card is inserted into the Vista, a cover is placed over its compartment, ensuring that the CF card cannot be accessed during the monitoring period.

5.1.2. The HolterSoft “Ultima” software

The software enables the computer to read CF cards recorded on a Vista.

The software, developed under MS Windows®, uses all the graphic possibilities of this platform: multi-windows, mouse, interactivity...

Reading the flash card and analysing the ECG on screen is done in just a few minutes.

The onscreen results can be checked from the patient’s heart rate trend, against which the physician can correlate histograms corresponding to the pathologies of interest. A single click on the heart rate trend curve, or on one of the histograms, immediately displays the corresponding ECG on different scales in the other windows.

Many other functions are also available, such as checking and reclassification of templates, searching for events according to pathologies, chronology or severity, scrolling the ECG, optional modules (Sleep Apnoea, AF,…).

HolterSoft also enables the recordings to be saved on a hard disk, so that they can, if required, be consulted at a later date; and several dozens of procedures (depending on the size of the hard disk) can be stored simultaneously and consulted or analysed again.

A fully customised report can be printed and can include any of the results visible on the screen, such as ECG extracts, tables of results, compressed ECG…

5.2. Vista display and keys

Vista general settings, or preparation for a new monitoring, are easily performed on the device itself, thanks to its 2 keys (**Select** and **Valid**) and its LCD display.

Either informative icons or option lists (items) can be displayed.

Generally, one item is selected (displayed in reverse video), and pressing **Select** key moves the selection from top to bottom.
When moving down the display tree, the upper item of each display is selected. When moving up the display tree, the previously selected item remains.

When the last item (most often **Back**, or **Next**) is selected, pressing again **Select** key moves the selection to the top item, and pressing **Valid** key moves to the next display (**Next**) or back to the previous one (**Back**).

On some informative displays, no options are available, so **Select** key is useless and pressing **Valid** key allows to go further.

The Vista automatically switches to a sleep mode if no key is depressed for two minutes. The current display switches off, except for 4 of them:
- Recording in process display (with a tape cassette as a symbol),
- Recording Over display, when CF card is full,
- Vista Ready display, following ECG test (§ 6.4.6 page 44),
- ECG display with no CF card inserted (see 5.3.3 page 26).

Pressing any key switches the display on again, at the previously selected point.

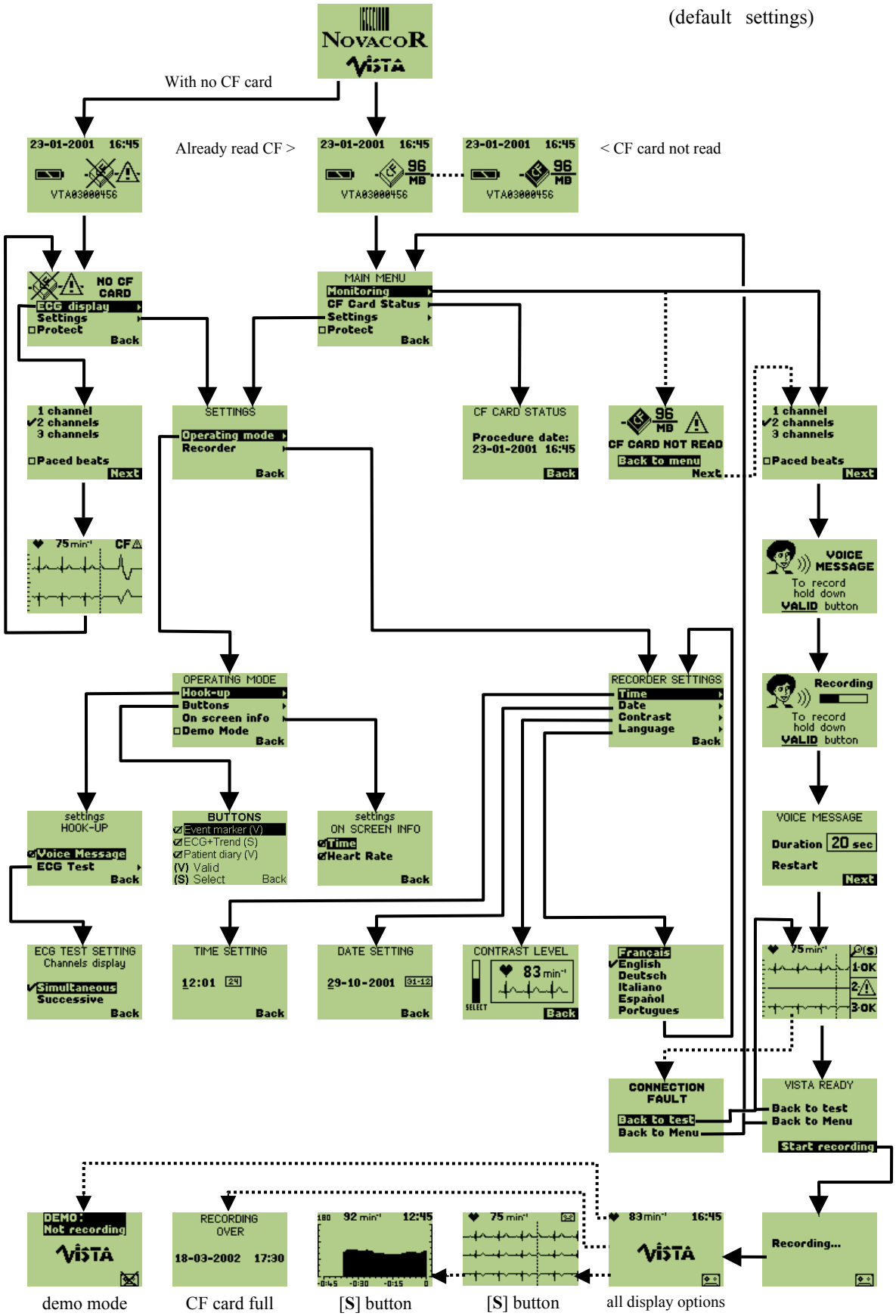
5.2.1. Check boxes and ticked lines

A line included in a multiple choice begins with a check box. When selected, pressing **Valid** key changes the box status (checked/unchecked).

A line included in an option choice does not begin with a check box. When selected, pressing **Valid** key ticks the line, even if it was already ticked, and unticks another ticked line in the same group, if any.

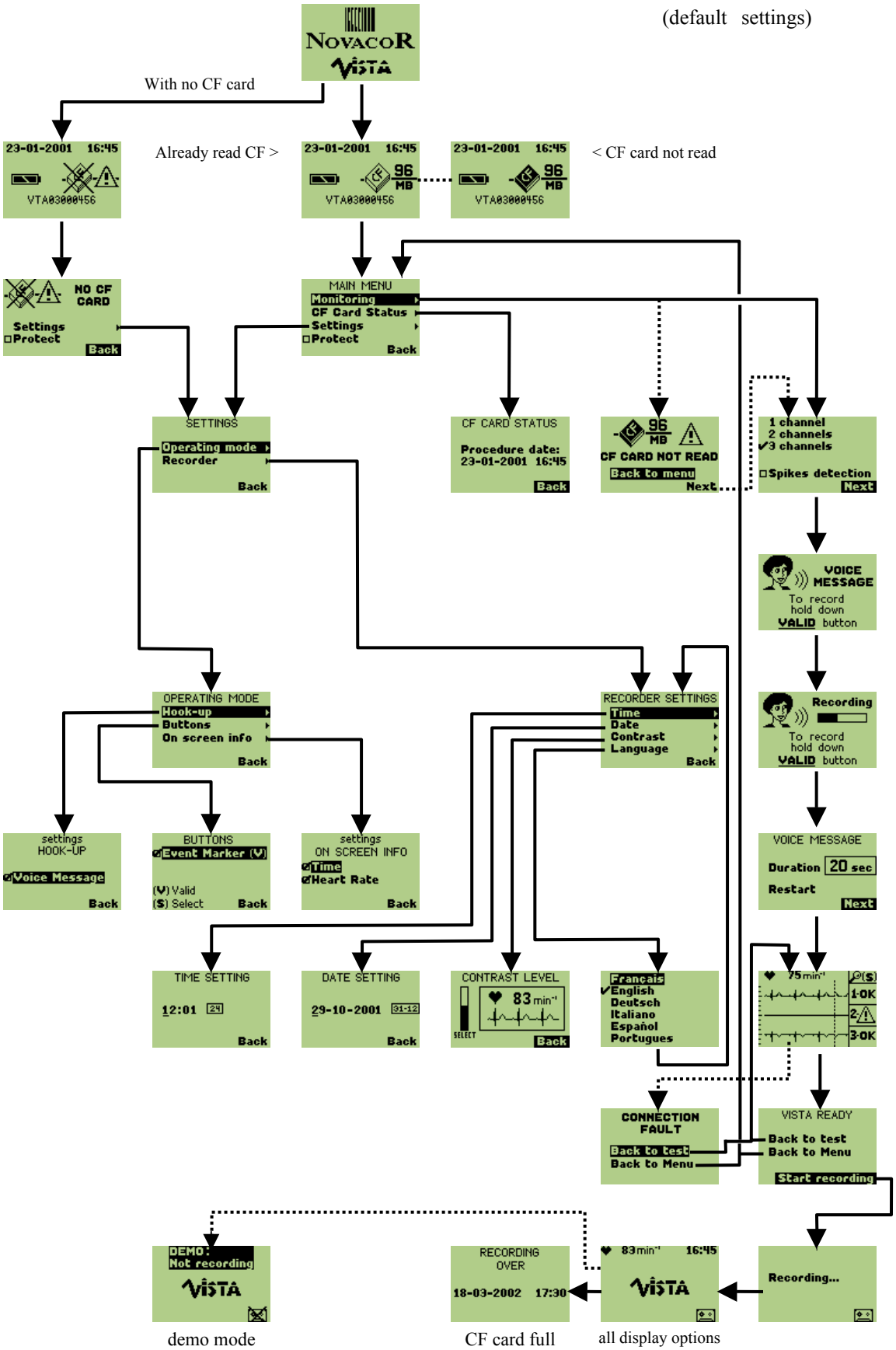
A line calling a submenu ends with a small arrow (triangle) on its right margin.

5.2.2. Displays flow chart (Vista, Vista Plus)



Back items with no arrow return to previous display.

5.2.3. Displays flow chart (Vista Access)



Back items with no arrow return to previous display.

5.3. Switching Vista on

5.3.1. Initial status

Welcome display (logos):

If any key is pressed or if a CF card is inserted whilst Vista (with batteries) screen is off,
or if batteries have just been inserted,
a welcome display is switched on for a few seconds.

The welcome display is then substituted for a status one, which informs about recorder and CF card status:

- present date and time,

- batteries information:

batteries not used yet for any 'start recording' since they have been inserted (most often: new batteries).

batteries which have performed at least one 'start recording' since they have been inserted.

- CF card information:

96 MB CF card containing a procedure which has been downloaded to a PC

96 MB CF card containing a procedure which has not been downloaded to a PC

No CF card

CF card not usable (defective or not Vista formatted)

- device status information:

recorder in demo mode

safeguard battery out of order (contact Novacor):
date and time are blinking because probably wrong.

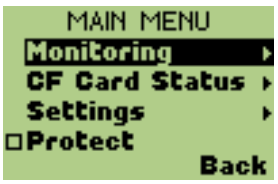
Example of status display:

- present date and time,
- batteries not used yet for any 'start recording' since they have been inserted,
- 96 MB CF card containing a procedure which has been downloaded to a PC,
- device serial number.

5.3.2. Main Menu with CF card

Only **Valid** key is active on Status display, and pressing it opens a *Main Menu*.

Main Menu:



This display offers 4 choices to the user:
- either initialise a monitoring,
- or display information about CF card content if any,
- or access to Vista settings,
- or avoid direct access to Vista settings.

(see § 5.3.4 page 27).

5.3.2.1. Choice 1: Monitoring

How to prepare a monitoring is detailed starting § 6.4.1 page 36.

5.3.2.2. Choice 2: CF Card status

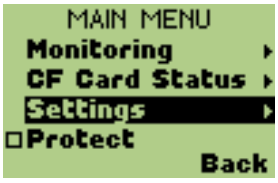
Valid *CF Card status* in *Main Menu* gives information about the procedure recorded on the CF card inserted in the Vista.

Corresponding display shows :
- either that the CF card is damaged or is not Vista formatted,
- or some data allowing to identify the recording:
  - patient name/1st name (if available),
  - date and duration of recording.

or

Select key is inactive,
and **Valid** returns back to *Main Menu*.

5.3.2.3. Choice 3: Settings



This mode, which does not require a CF card inserted, is detailed ahead in § 7 page 49.

Selecting and validating **Settings** in *Main Menu* allows to define:
- all basic recorder settings (date, time, display formats, languages, etc.),
- the start up sequence,

and, if necessary, to turn the Vista in « demo mode » in order to simulate the way it works, but without possibility to record any signal.

5.3.3. Using Vista to only display ECG (except Vista Access)

When no CF card is inserted, it is possible, besides adjusting its settings, to use the Vista to display a continuous patient's ECG.

5.3.3.1. Status display with no CF card

In Status display, a specific pictogram immediately advises that no CF card is inserted.

(Vista all models)

5.3.3.2. Main Menu display with no CF card

Then the *Main Menu* offers only:

- ECG display (except Vista Access),
- or recorder settings (with protection possibility),
- or cancel, by validating **Back** .

5.3.3.3. ECG display (except Vista Access)

Pressing **Select** key once then **Valid** will turn the Vista in ECG display mode:

It is possible then to indicate:

- how many channels are connected,
- if the patient wears a pacemaker,

using **Select** and **Valid** keys to change the purposed program (see § 6.4.2 page 37).

For 1 or 2 channels, any one can be chosen since the standard cable allows to connect independent bipolar channels.

For 3 channels, the cable collects 3 bipolar channels with a common point on the sternum (see connection § 6.1.3 page 32).

Validating **Next** starts ECG display, only as defined for simultaneous mode ECG test § 6.4.5 page 43, with the difference that display will not stop until **Valid** key is pressed again (**Select** key is used to zoom on one channel).

5.3.4. The Protect feature

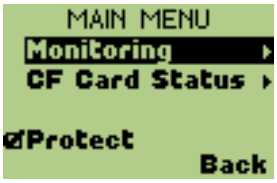
In order to avoid immediate or too much easy access to the Vista settings, it is possible to remove the **Setting** line from *Main Menu* (a CF card being inserted or not).

In *Main Menu*:

select and valid **Protect**.

Protect box is then checked.

If coming back later in the *Main Menu*, the **Settings** line will not be displayed any more :



Direct access to Vista settings is not possible any more, thus making more difficult to change them.

To get the settings available again, just perform the reverse operation:

- select and valid **Protect** item, which unchecks its box,
- exit from *Main Menu* by selecting and validating **Back**,
- go back to *Main M*enu.

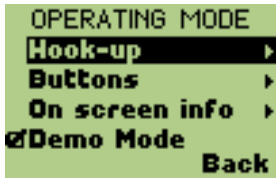
5.3.5. The « demo »mode (except Vista Access)

The demo mode allows performance of a normal hook-up sequence without connecting the Vista to a patient.

Inserting a CF card is required for recording simulation, but since real recording will not be allowed, CF card content will not be altered.

Just check **Demo Mode** on *Main Menu / Settings /Operating Mode* display to set the demo mode.

This box will have to be unchecked at the moment to recover the normal mode.



Recording a voice message can be normally done in Demo Mode, but since it is a simulation it will not be possible to replay it.

ECG test will be simulated as well: an ECG diagram is specially memorized for that purpose. This memorized diagram can be displayed in Demo Mode only.

After simulated recording has started, just press **Valid** key to go back to the *Main Menu*.

6. Monitoring

Preparing to monitor with the Vista is quite easy and fast, and can be achieved in the following order:

- Place electrodes on the patient
- Insert the batteries into the unit, if necessary
- Insert the CF card into the unit
- Prepare the unit
- Connect the unit to the patient
- Perform ECG test, and start.

Once the monitoring is over, CF card is taken out from the recorder and downloaded to a computer.

6.1. Placing the electrodes on the patient

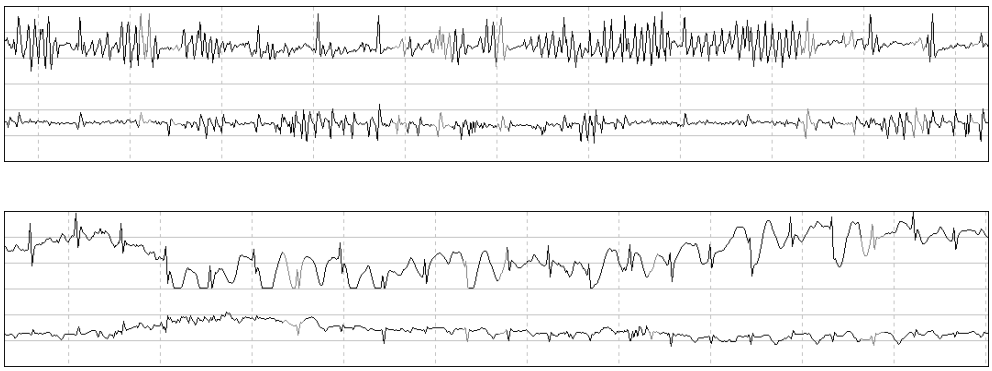
6.1.1. Preparation

The high accuracy and reliability of the Vista recorder means that quality of recorded signal mainly depends on each part of the recording elements: electrode-skin contact, type of electrodes, condition of contacts and connectors.

The patient's skin must be perfectly dry and cleaned (preferably dry cleaned with special scraper) before putting the electrodes in place.

Long term monitoring electrodes, generally specified for Holter monitoring, must be used and manufacturer recommendations must be carefully followed.

Diagrams collected with inappropriate electrodes:



The impedance between electrode and skin decreases a few minutes after the electrodes are placed on the patient.

So it is recommended to place the electrodes on the patient before preparing the Vista, because the lower the impedance the better the signal quality.

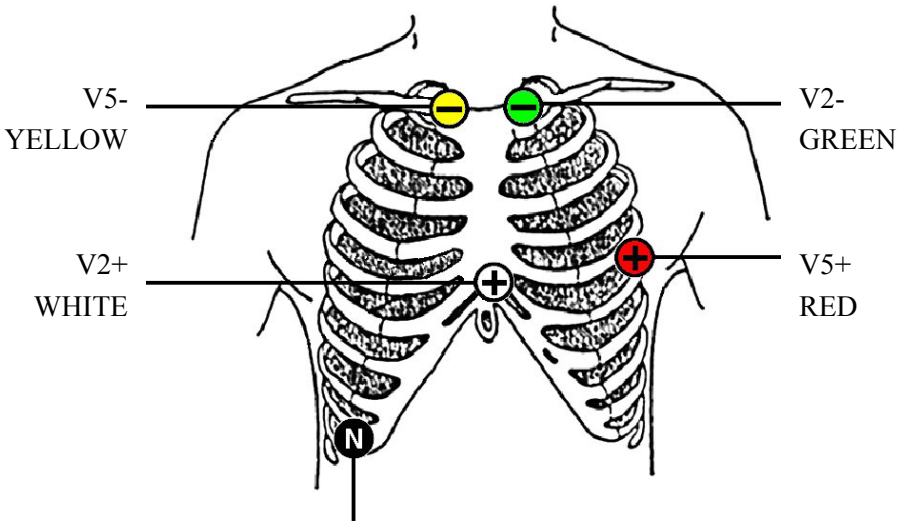
The following sketches show a possible way to place the electrodes on the patient. The colours given to the electrodes are those of the connectors of the 5 wire ECG cable supplied by Novacor.

6.1.2. Two channel recording

To record 2 channel ECG, either the standard cable or special 'Thorax' cable can be used.

Most often, recommended configurations are the modified V5 and V2 leads, located as follows:

+ Channel 1:	RED	V5+	5th intercostal space, left axillary line.
- Channel 1:	YELLOW	V5-	Right clavicle, at the sternum border.
+ Channel 2:	WHITE	V2+	Lower right of the sternal edge.
- Channel 2:	GREEN	V2-	Left clavicle, at the sternum border.
	BLACK	Neutral	Rib cage, lower right part.



Of course, the suggested electrodes dispositions are only examples given as information. The practitioner will choose the most appropriate channel disposition, especially for the third channel, according to his own criteria.

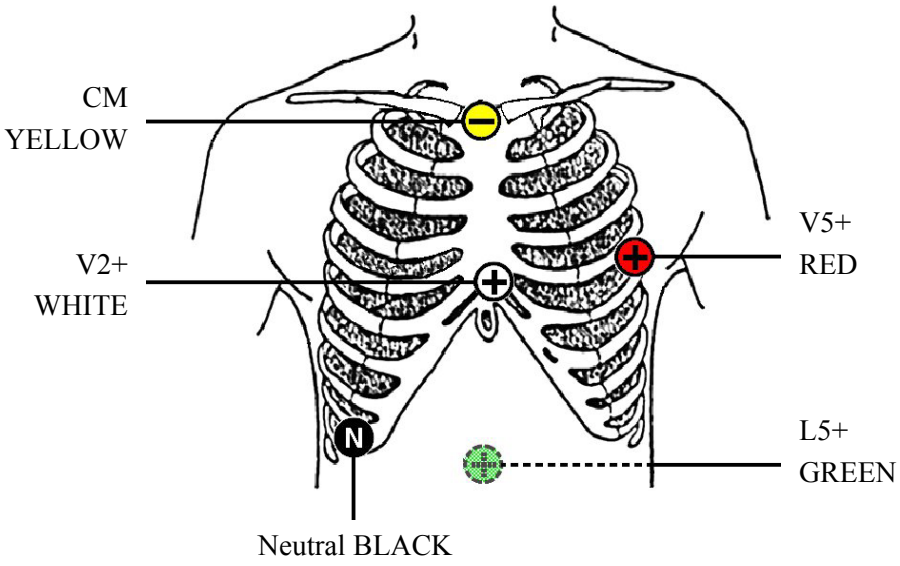
Especially, if channel 2 voltage is poor, positioning the white electrode slightly more to V3 point results in a higher signal (remove and throw away the electrode, clean the skin and place a new electrode).

6.1.3. Three channel recording

Three channel ECG recording must be performed using standard 5 lead ECG cable.

The two first channels are almost the same as in two channel recording, the two upper electrodes being replaced by one only which is used as a common point for the three channels. Channels CM5, CM2 and CML5 will be so achieved if the third electrode is located in L5.

+ Channel 1 :	RED	V5+	5th intercostal space, left axillary line.
- Channel 1 :	YELLOW	CM	Common, upper part of sternum.
+ Channel 2 :	WHITE	V2+	Lower left of the sternal edge.
- Channel 2 :	YELLOW	CM	Common, upper part of sternum.
+ Channel 3 :	GREEN	L5	L5
- Channel 3 :	YELLOW	CM	Common, upper part of sternum.
	BLACK	Neutral	Rib cage, lower right part.



Alternatives for three anterior channels:

Green electrode in V4R, or green electrode in V4 and red electrode in V6.

The green electrode could also be placed higher in the back, in front of V2, offering another interesting antero-posterior channel.

6.2. The Batteries

6.2.1. Type

The Vista works with two alkaline standard 1.5 V AAA/ LR03 type batteries for an optimised energy to weight ratio. These batteries are specially adapted for use with the Vista and one pair of batteries enables at least four 24 hour 2 channel monitorings.

You may also use standard rechargeable batteries, NiCd or preferably NiMH type. This results in reduced autonomy, according to the model of battery used.

Batteries can be inserted in the Vista with or without CF card inserted before.

6.2.2. Inserting the batteries

- Take off the cover.
- If batteries are already in the unit, remove first the furthest one away from the edge, taking care to lift it up by the positive polarity (+).

When inserting the new batteries, take care not to invert the polarities:

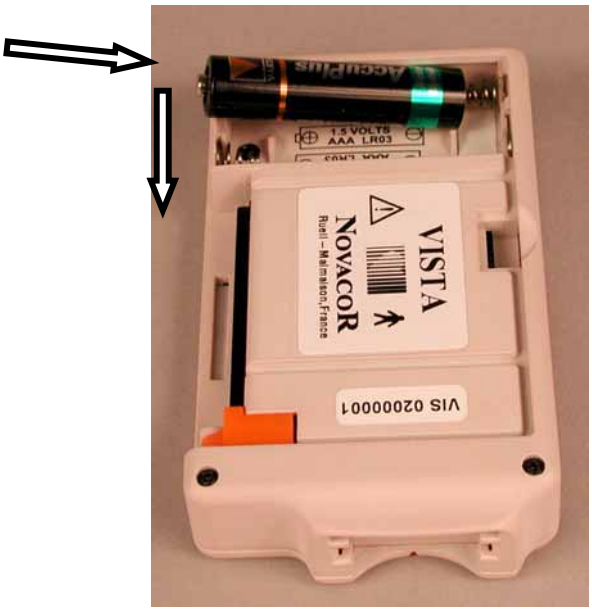
- Start by inserting the battery closest to the edge.
- The + and – signs on the battery should be oriented as indicated on the unit. Insert the negative extremity first, then push down the other end of the battery.
- A beep confirms that the batteries are in place.

  Then a welcome display turns on, replaced after two seconds by another one which gives information about the device ("Status" display).

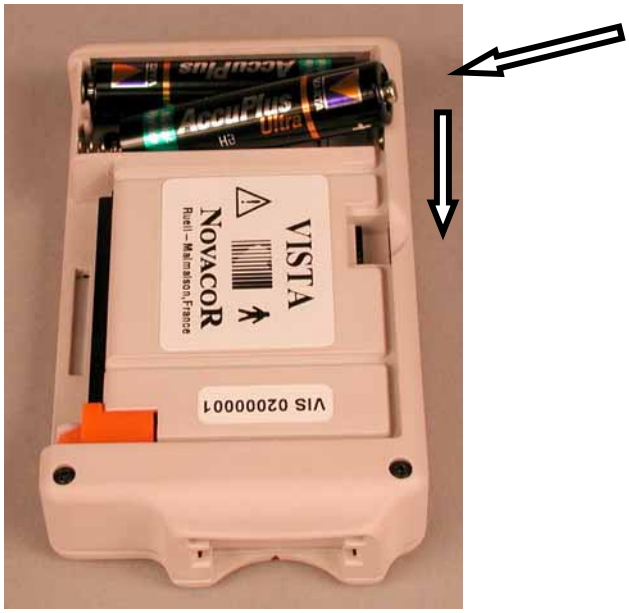
  This display auto shuts off after 2 minutes if the Vista is not operated.
- If you find it particularly difficult to insert a battery, **do not force it**. Check that you have followed the above instructions carefully before giving it another try.
- If needed put in place a CF card for a new recording (cf ahead § 6.3).
- To close the cover back: insert the cover pivoting tab into the corresponding slot in the Vista, and gently close the cover until it locks. During the operation, continuously check correct cover position.

Special care with batteries:

- Do not invert the polarities.
- Do not store them over 45°C.
- Check the batteries before each new procedure.
- Do not store a Vista containing discharged batteries.
- Do not leave the batteries in the Vista for more than a month if not in use.



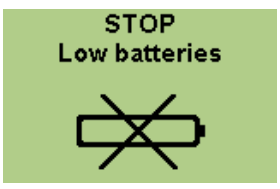
Inserting the first battery



Inserting the second battery

6.2.3. Low batteries

When inserting either batteries or batteries and CF card, if the remaining capacity of the batteries is too low, a warning message is displayed on the Vista : the batteries must be replaced to go on.



This message can also be displayed when removing the CF card after that a recording stopped because of low batteries.

Of course if the batteries are totally exhausted the message will not be displayed.

6.3. The Compact Flash card

Novacor supplies CF cards specially formatted for the Vista.

6.3.1. CF card size

It depends on the maximum desired recording duration :

CF card size	Maximum recording duration (except Vista Access)		
	1 channel	2 channels	3 channels
96 MB	4 days	2 days	1 day
128 MB	6 days	3 days	2 days
256 MB	11 days	6 days	4 days
512 MB	11 days	11 days	8 days

With the Vista Access, the recording duration is always limited to 24 hours, regardless number of channels (1, 2 or 3) or CF size.

6.3.2. CF card insertion

The CF card can be inserted in the Vista unit before or after the batteries.

Care CF card positioning!

Wrong CF card positioning during insertion, especially 90° badly oriented, can seriously damage the Vista unit, thus resulting in an expensive repair not covered by warranty (incorrect use).

- Turn the device over (screen side down) and remove cover.
- Insert the CF card into its compartment, making sure that it is down flat, with the arrow on top and pointing towards the unit.
- Push the CF card in without forcing it, until you feel a slight resistance while some millimetres are still missing.
- Push a little harder so that the CF card goes into its connector.

  If batteries were in place:

  A beep sounds, the current display switches off, and a welcome display turns on. After a few seconds with fast beeps, another display (“Status” display) will give information about the new device status.

  This display auto shuts off after 2 minutes if the Vista is not operated.

Caution!

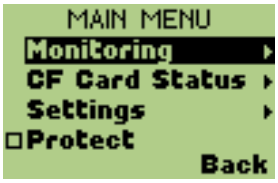
- If there is a lot of resistance, this means that the CF card has probably been inserted upside down. Remove it, turn it round and try again.

6.4. Starting the device

In order to perform a new monitoring, adequate batteries and CF card must have been inserted into the Vista.

Pressing **Valid** key when Status display is on (§ 5.3.2 p 25), shows the *Main Menu* where **Monitoring** is selected by default.

6.4.1. Monitoring



Press **Valid** key to initiate Vista monitoring start up sequence, i.e.:

- Confirm or modify previously used program.
- Execute start-up option possibly defined in device settings (recording a voice message).
- Display ECG test on Vista.
- Start monitoring.

6.4.1.1. Procedure not downloaded

If the procedure recorded on the just inserted CF card has not been transferred to a PC, a warning is displayed:

'CF Card not read' warning:

This display offers the user 2 choices:

- either stop start up in order to use another CF card, by validating **Back to menu** (pre-selected),
- or go on with this CF card for the new monitoring, selecting and validating **Next**. Data on the flash card will be erased.

6.4.2. Monitoring Program

The next display shows the program used for the previous monitoring performed with the recorder.

Program display **:**

Next is pre-selected, so only pressing **Valid** key allows to use the same program and shows the next display.

To change the number of channels, just **Select** and **Valid** the new value.

Example :

Select 3 times:

then **Valid**:

finally **Select** :

So we changed the program in order to record 3 channels instead of 2, still for patient with no pacemaker.

If we would have wished to add that the patient is equipped with a pacemaker in the above sequence:

from display

Valid :

then **Select** :

After validating **Next** we jump to the next display.

6.4.2.1. Continuing Vista Hook up

The next step in Vista preparation (voice message recording) will be proposed only if it had been set in recorder settings (§ 7.3.1 p 54).

If not, validating **Next** in *Program* display will jump to the *Vista ready* display (§ 6.4.6 p 44).

6.4.3. Voice Message

If this option had not been set, Vista directly jumps to ECG test.

The Voice Message display allows to verbally record, for example, patient's ID and date of birth, or any other brief relevant information.

It will be possible to listen to the recorded message on the PC, as many times as necessary, after procedure is downloaded from CF card to PC.

The user will maintain **Valid** button pressed down as long as speaking. During this time, a gauge shows the elapsed time (maximum recording duration 20 seconds).

When releasing **Valid** button:

- voice message recording stops,
- confirm message is displayed.

The user can now :

- either go on by pressing **Valid**,
- or jump back to voice message recording, pressing first **Select**, that selects **Restart**, then **Valid**.

  The latest recorded voice message is then erased.

Next step in Vista preparation is ECG test, so at this time the Vista must be connected to the patient.

6.4.4. Placing the Vista

The electrodes are already placed on the patient (§ 6.1p 30).

Most often, to avoid too many manipulations of the cable, it stays connected to the Vista, except of course if a different one must be used.

It is however important to know how to proceed for Vista cable connection or disconnection.

6.4.4.1. Connecting the ECG cable

Pull the connector cap back a few centimetres.

Connect the ECG cable to the unit.

The logo of the cable (with a red triangle) should be facing the front panel of the Vista. Push the cable into the connector until it clicks into place.

Inserting the connector

Push the cap back over the connector, making sure that the two side clips have clicked into place.

Placing the connector cap

6.4.4.2. Disconnecting the ECG cable

It is important that the different steps be followed in order, to avoid damaging the connectors.

First pull only the cap back, by pressing on each side and sliding it back a few centimetres.

Before pulling the cable out, the connector must be unlocked. It should never be forced or the unit could be damaged!

Firmly pinch the connector between two fingers and then pull it out.

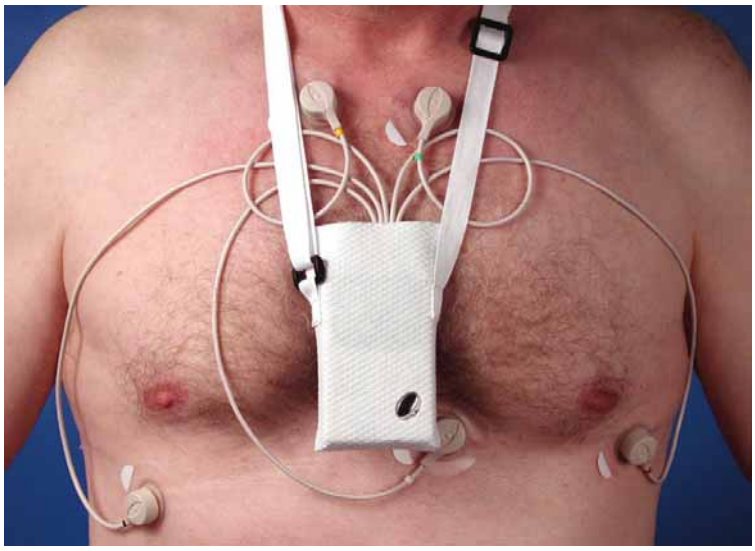
Never pull on the cables!

6.4.4.3. The final step for unit placement

After having inserted the Vista in its pouch and connected the ECG cable, the unit must be placed on the patient.

6.4.4.3.1. Placing on the chest

Suspend the neck pouch around the patient's neck and connect the 5 wires to the corresponding electrodes in place on the patient, in accordance to the indications given page 31.



Vista placed on the chest, in medium position

The unit can be placed from high on the chest to rather low, practically on the solar plexus, according to the patient's morphology and feeling, by adjusting the length of the strap around the neck.

On the back of the 'neck' pouch a pressure clip has been fixed. It can be clipped to an adhesive patch (or an extra electrode, preferably dry) placed on the patient's skin in order to prevent the device moves.

The neck pouch is not single use one but cannot be re-used a very high number of times.

It is recommended to wash it between each patient (see § 8.2 p 60).

Packs of 5 units are available at your Novacor's supplier.

6.4.4.3.2. Installing with the belt or the shoulder strap

Thread the belt through the pouch (or hook the shoulder strap) and place the belt on the patient. Adjust its length if necessary.

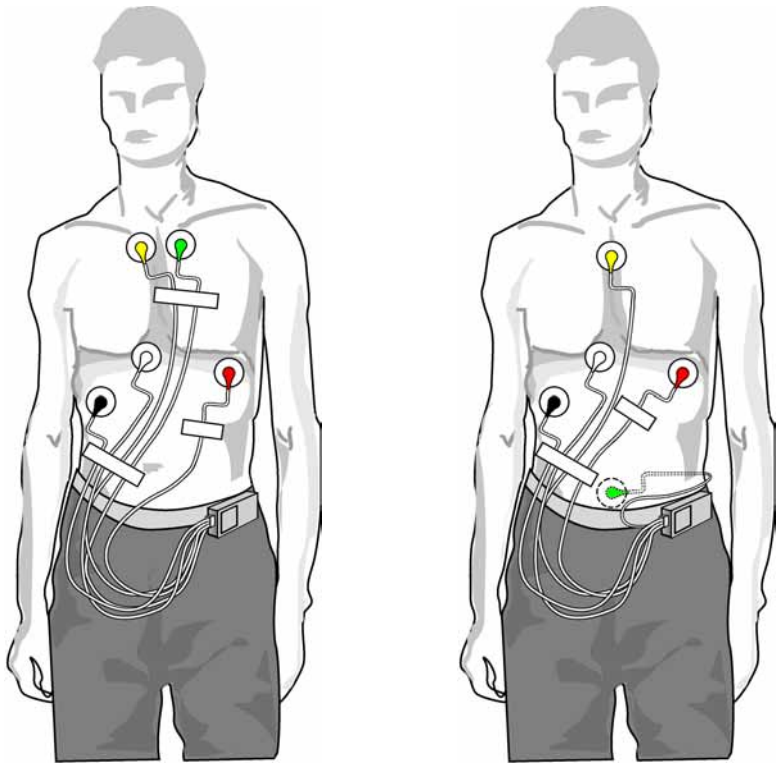
It is advisable to place the belt over the patient's clothes in order to avoid any possible skin irritation due to contact with the belt or the pouch.

Connect the ECG cable to the electrodes on the patient, following the diagram described page 31 (2 channel recording) or page 32 (3 channel recording).

If you wish you can use adhesive pads to maintain the ECG leads in place and proceeding in the usual manner when placing a Holter ECG.

Since any movement on a wire must not be transmitted to the electrode, it will be helpful to fix a piece of adhesive rubber at a few centimetres distance from the electrode, keeping a small loop of wire between the electrode and the adhesive rubber.

If after a certain time using a given ECG cable with no problem, artefacts appear more and more in the recordings, thought should be given to replacing the worn or damaged cable.



two channel connection *three channel connection*

Patient equipped with the standard or long ECG cable

6.4.5. ECG test

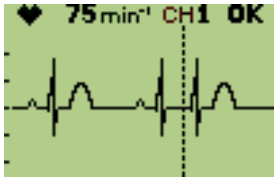
Patient's ECG is displayed automatically, together with the heart rate and information about signal quality, according to the setting made in *Start up / ECG test* (§ 7.3.1.1 p 55) :

- either all channels one by one, alternating every 10 seconds (except Vista Access),
- or all channels simultaneously (all models).

As many channels will be displayed as set in the monitoring program (§ 6.4.2 p 37).

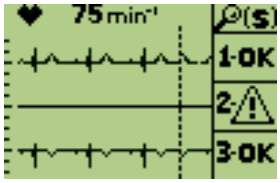
6.4.5.1. Alternating ECG display (except Vista Access)

ECG channel 1 according to 'Channels display: Successive'.
After 10 seconds, it will be replaced with channel 2, etc.



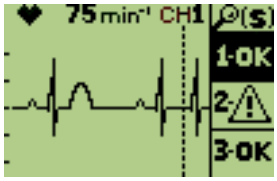
6.4.5.2. Simultaneous ECG display

ECG display according to 'Channels display: Simultaneous (example with 3 channels).



In this mode, it is possible to zoom any single channel, pressing **Select** key, which displays first channel 1 alone, then channel 2 alone, then channel 3, then again the 3 channels,…

Zoom on one channel:
Example pressing **Select** key once in simultaneous display.



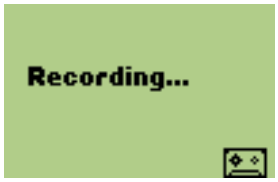
During ECG test, signal quality is checked and indicated: **OK** is displayed if it looks good, and ⚠ if not.
If all channels are so labelled (not good), monitoring will not start.

Next display is automatically shown after 1 minute, or earlier by pressing **Valid**.

6.4.6. Confirm and start monitoring

A confirm message is displayed before starting the recording, just in case the user would like to check or change some start up conditions.

It is possible to perform again the whole Vista hook-up, choosing '**Back to Menu** (back to *Main Menu* display), or the ECG test only, choosing '**Back to test'**.



Valid on '**Start Recording'** starts monitoring, which will be indicated this way for 2 seconds.

After the 2 first seconds of monitoring, the permanent display will be shown, according to the device settings.
(example with time + HR)

The demo mode is displayed too if switched on, because in the demo mode no record can be made and you just have to press **Valid** to go back to the *Main Menu*.

6.4.6.1. Connection fault

If all channels exhibit the not good icon ⚠ at the end of ECG test, the above *Vista Ready* display will be replaced with this display, and recording will not start.

6.5. Use of the buttons during recording

During the monitoring, if the buttons have been activated (see § 7.3.2 p 56), they can be used in different ways according to the Vista model.

6.5.1. 'Patient' button (Valid)

6.5.1.1. All models : event marker

Briefly press the **Valid** button (during 0,2 s) and then release it to add an event marker on the recorded ECG.

The patient must then write down in his diary the reason why he marked this time (symptom, particular activity,…).

6.5.1.2. Vista Plus: voice diary

If the "voice diary" function has been activated from the setup menu, the recorder emits a first beep when the patient press the **Valid** button (thus adding an event marker to the recorded ECG as described in the previous paragraph) . It the **Valid** button is maintained pressed down after this beep, the Vista Plus emits a second different sound after 0.5 s, to advise that the built-in microphone is switched on.

As long as the patient maintains the button pressed, he can perform an audio recording of his diary, instead of writing it down. He must only speak clearly, without moving the unit.

The audio recording stops as soon as the key is released. Once started, a voice message lasts at least 2 s, even if the key is released before. When a voice message is finished, it is possible to begin another one immediately.

The recording duration of each message is not limited, but the cumulated duration of all the diary messages cannot exceed 5min40s.

6.5.2. 'Physician' button (Select)

This feature is not available on the Vista access.

Select button if active during the monitoring allows to display the patient ECG in real time, all recorded channels simultaneously, and a heart rate trend on the last 12 hours as a maximum (16 hours for Vista Plus).

6.5.2.1. 1st press: real time ECG

A 1st press on the **Select** button, until the Vista emits a sound (after about 0.2 s) triggers the display of the ECG for 1 minute, then the display turns back to normal.

6.5.2.2. 2nd press: heart rate trend

If the **Select** button is pressed again during the real time ECG display, it will be substituted by the patient heart rate trend, also for 1 min maximum. Pressing again the **Select** button turns the display back to normal.

The sampling period of the heart rate trend depends on its duration:

Trend duration					
Vista	< 45 min	from 45 min to < 1,5h	from 1,5 h to < 3 h	from 3 h to < 6 h	from 6 h to 12 h
Vista Plus	< 1 h	from 1 h to < 2 h	from 2 h to < 4 h	from 4 h to < 8 h	from 8 h to 16 h
Sampling period	30 sec	1 min	2 min	4 min	8 min

6.6. Downloading the procedure

6.6.1. End of monitoring

The duration of monitoring does not need to be programmed: recording stops when the CF card is full or removed from the unit, or if the batteries are too weak.

This message is displayed when the CF card is full, or when the remaining energy in the batteries is too low to go on recording.

In this last case, after removing the CF card, the message « Low batteries » is displayed (cf § 6.2.3 p 34).

- In the Vista Access, only the first 24 hours will be kept.
- Once CF card is removed, the recording cannot take place anymore.
- If the recording lasts more than necessary, it is possible to shorten it (to 24 or 48 hours for example) after download to the computer.

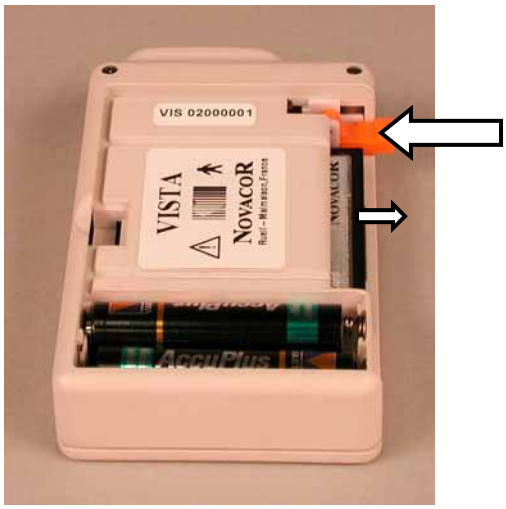
Caution !

Always disconnect the ECG cable from the electrodes placed on the patient before unplugging the cable from the unit.

6.6.2. Transfer to the computer

- disconnect the ECG cable from the electrodes,
- un-strap the belt and remove any remaining wires or electrodes from the patient,
- remove the unit from the pouch,
- open the CF card/battery cover,
- remove the CF card :

extend the pushrod



firmly press on pushrod to eject CF card

- insert the CF card into the corresponding drive,
- then proceed to recording download with HolterSoft *Ultima* software.

7. Vista settings

To get the best from Vista, its settings must be optimised according for example to the country where it is being used, and to the users' preferences.

Some settings are rather general ones:

- language, display formats,
- date and time settings.

Other settings are more a customisation of the unit:

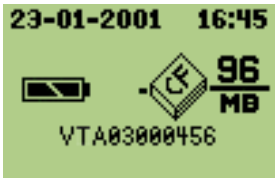
- contrast adjustment,
- hook-up operation,
- Vista displays and buttons action during recording.

These settings are done directly from Vista display, as described here after.

Please note that serial number can be set only at Novacor's.

7.1. Settings mode

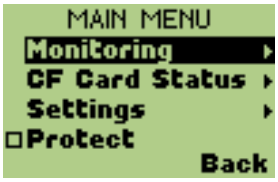
Settings mode can be reached with or without CF card inserted in the unit, starting from Main Menu (§ 5.3.2 page 25).



Example from *Status* display:

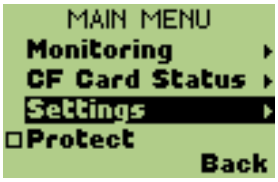
Status display

Valid :



Main menu

then **Select** twice:

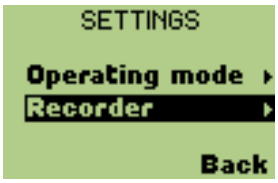


then **Valid** shows >

From *Settings* display it is possible either to access recorder settings or operating mode settings (preferences for device set up and monitoring, or switching the unit in Demo mode).

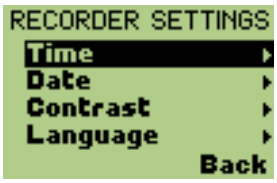
7.2. Recorder settings

General Vista settings are reached by validating **Recorder** from *Settings* display:



Settings display

Recorder Settings display



7.2.1. Time adjustment

Valid **Time** (default selection) from previous display.

24:00 or AM/PM formats are available.

When displaying, the 1st digit of the time is selected, if we validate we jump to the 2nd digit.

Select offers successively all possible values (0 ; 1 ; 2 for the 1st digit in 24:00 format), then

Valid jumps to next digit, and so on.

Valid on the 4th digit confirms Vista time and selects the current time format.

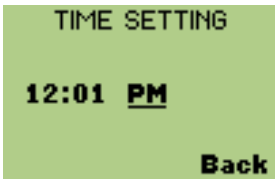
Valid confirms this format and jumps to **Back**.

Valid on **Back** goes back to previous display, with **Time** selected.

7.2.2. Time format

When the time format is selected, **Select** toggles successively from **24** to **AM**, then to **PM**, then to **24** again, etc.

To change time format, **Select** and **Valid** the new one:

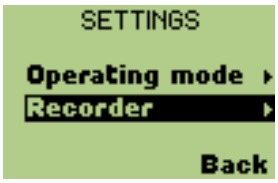


For example, **Select** 3 times on **24** selects **PM**.

Valid then confirms the new format and jumps to **Back**.
Valid on **Back** goes back to previous display, with **Time** selected.

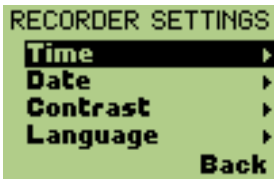
7.2.3. Date adjustment

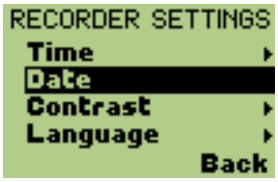
Get *Recorder Settings* display from *Settings* display:



Settings display

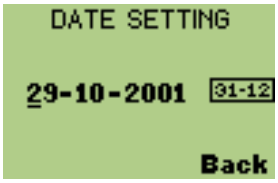
Recorder Settings display





From *Recorder Settings* display, select and valid **Date** to access *Date Setting* display.

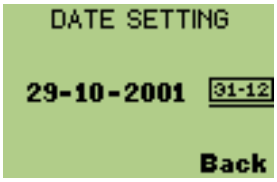
Two formats are available, symbolized by 31-12 (day first) or 12-31 (month first).



When displaying, the 1st date digit is selected, if we validate it is confirmed and we jump to the next digit.

Select offers successively all possible values (0 ; 1 ; 2 ; 3 for the 1st digit in 31-12 format), then

Valid jumps to the next digit, and so on.



Valid on the last digit confirms Vista date,
and selects the current 'date format'.

Valid confirms this format and jumps to **Back** .

Valid on **Back** goes back to previous display, with **Date** selected.

7.2.4. Date format

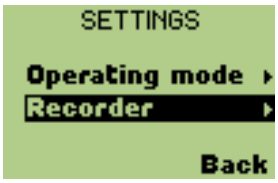
From *Date setting* display, with **31-12** selected, **Select** toggles successively from **31-12** to **12-31**, then to **31-12** again, etc.

To change date format, **Select** and **Valid** the new one.

Valid then on **Back** goes back to previous display, with **Date** selected.

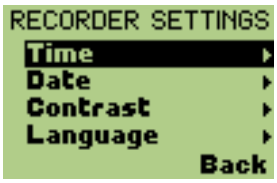
7.2.5. Contrast adjustment

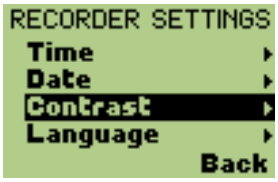
Get *Recorder Settings* display from *Settings* display:



Settings display

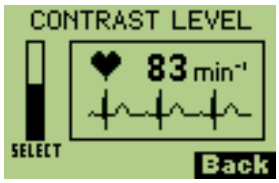
Recorder Settings display





From *Recorder Settings* display, select and valid **Contrast** to access *Contrast Level* display.

Contrast Level display



On this display it is possible to adjust contrast level (5 levels) and check the result in the same time.
The contrast level corresponds to the bar graph position.

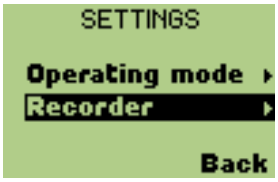
When displaying, the bar graph position corresponds to the actual contrast level, and **Select** increases the level by one step.

After level 5, it starts again from level 1.

Valid goes back to previous display, with **Contrast** selected.

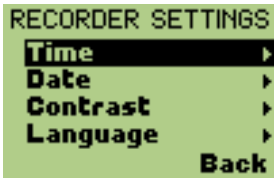
7.2.6. Choosing the language

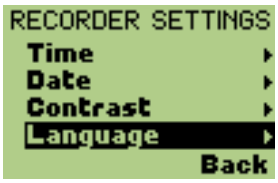
Get *Recorder Settings* display from *Settings* display :



Settings display

Recorder Settings display





From *Recorder Settings* display, select and valid **Language** to access corresponding display.

Language display

When displaying, the current language is checked and **Français** is selected.

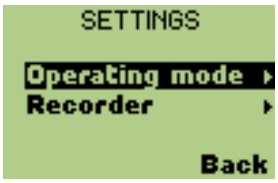
Select successively goes over all languages.

Valid one of them :

- checks the item,
- activates the new language, and
- goes back to previous display, with **Language** selected.

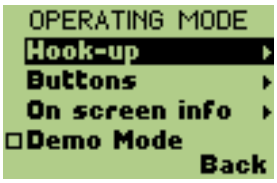
7.3. Operating Mode setting

Preferential user's settings for Vista operation during hook-up and during monitoring can be adjusted after validating **Operating mode** (default setting) from *Settings* display:



Settings display

Operating Mode Settings display



(*Demo Mode* item is not displayed on Vista Access)

This display *Operating Mode Settings* allows:

- choosing **Hook-up**,
  to define Vista hook-up sequence,
- choosing **Buttons**,
  to set patient button (**Valid**) and (except for Vista Access) physician button (**Select**) functions during recording,
- choosing **On Screen Info**
  to list the permanent displays during the whole monitoring.

Press **Valid** key for display corresponding to the item selected with **Select** button.

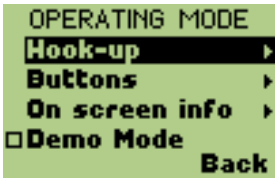
Besides the above choices, if the **Demo Mode** box is checked, it becomes possible (except for Vista Access) to perform a normal hook-up sequence without connecting the Vista to a patient (see § 5.3.5 page 27).

7.3.1. Hook-up setting

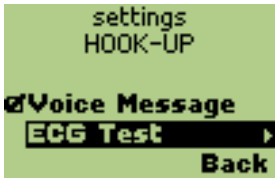
The hook-up phase includes all the operations that must be achieved, when initiating a new monitoring, from insertion of a CF card in the Vista, to the beginning of recording.

Hook-up, as defined in § 6.4.1page 36, always begins with confirmation or modification of the previously used monitoring program, and goes on with the following steps:

- recording a voice message (20 seconds max), allowing for example to record patient ID (optional step),
- checking correct cable connection and signal capture, displaying patient's ECG (all channel ECG test) before starting recording (step not optional).



Selecting and validating **Hook-up** in *Operating Mode* display gives access to these choices.



Settings/Hook-up display

(*ECG Test* item is not displayed on Vista Access)

Select allows to choose an item the status of which must be changed.

Selecting and validating **Back** immediately sends back to previous *Operating Mode* display.

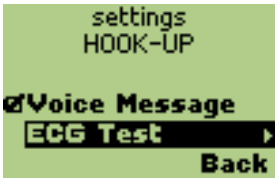
If **Voice message** is not ticked, it will not be proposed to the user when starting the Vista.

The way the patient's ECG will be displayed during ECG test (except for Vista Access) is defined by selecting and validating **ECG Test**, as described right after.

7.3.1.1. ECG Test: simultaneous or successive

Please note that Vista Access does not offer this choice, its ECG test being always performed in simultaneous mode.

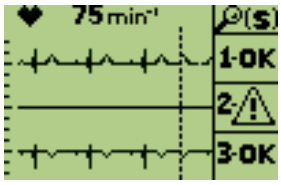
Validating ECG Test item in *Settings Hook-up* display allows to define the way the patient's ECG will be displayed on Vista during ECG test.



ECG Test display

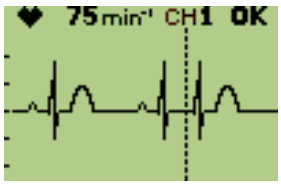
7.3.1.1.1. Simultaneous display

This way all programmed channels will be displayed simultaneously, as would do a multi-channel ECG machine.



Example with three channels

7.3.1.1.2. Successive display



Channel 1 is displayed first during 10 seconds, then channel 2 instead, and so on.

All programmed channels will be shown in loop.

Once the choice **Simultaneous** or **Successive** is done, selecting and validating **Back** returns to previous display.

7.3.2. Buttons setting

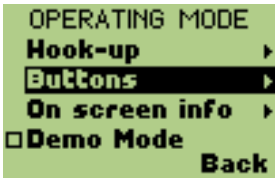
During the monitoring

- **Valid** becomes the « patient button»: event marker and/or, on Vista Plus, audio recording of the patient diary.
- **Select** (except for Vista Access) becomes the « physician button » .

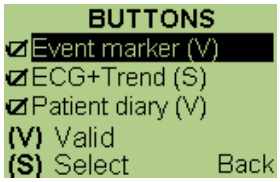
To the user's choice, pressing patient button (**Valid**) during recording can have no action at all (button not activated), or can result in writing a marker on the patient's ECG. This event marker can be then located on the PC after analysis ; generally the patient notes in his diary the reason why he marked the ECG (symptom, specific activity,…).

In the same way, pressing physician button (**Select**) for about half a second allows to successively display ECG diagram and Heart Rate trend.

From *Operating Mode Setting* display:



Valid on B**uttons** selection displays the corresponding menu.



Buttons setting display (Vista Plus)

In this *Buttons* menu:

Select goes successively over the possible options, and

Valid toggles the status of the selected item without moving the selection.

Selecting and validating **Back** returns to previous display.

If the « physician button » (ECG + trend) is active, a first press on it (for about half a second) during monitoring will display the patient's ECG, in simultaneous mode, for 1 minute.

When pressing **Select** a second time (for about half a second as well) during this minute, the ECG is replaced by the patient's heart rate trend, on the last 12 hours as a maximum.

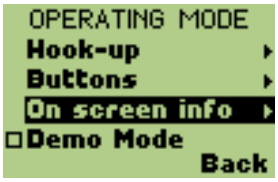
Pressing **Select** a third time removes physician display.

On Vista Access, **Select** button is never active during recording.

7.3.3. On Screen Info setting

This setting corresponds to the information which appears permanently on Vista display during the whole monitoring.

From *Settings / Operating Mode* display:



Validating **On Screen Info** opens the corresponding menu.

If no item are selected, Vista displays only a simple icon (cassette tape), plus the Vista logo, to indicate that it is recording.

Selecting then validating one or several options from *On Screen Info* setting display, the following displays can be added by the user:

- Vista time, and/or
- patient heart rate (mean on the last 4 beats).

Vista display, during monitoring, with both display options:

Both options are ticked.

resulting Vista display

Validating **Back** returns to previous display.

8. Precautions when using Vista

8.1. Handling the equipment

Placing the unit on the patient must be carried out by qualified medical staff.

Do not use your nails or a sharp object when pressing Vista keys.

The Vista is not completely hermetic, therefore it should not be exposed to dust or humidity and care must be taken to ensure it is never sprayed with or immersed in water.

Vista recorder has not been designed to be placed on children less than 10 kg.

8.2. Cleaning the equipment

Clean and disinfect the Vista regularly with a soft cloth, lightly moistened with spirit or a cleaning product containing neither solvents nor detergents.

It is recommended to clean the ECG cables between each patient.

Avoid all contact with liquids.

Clean the neck pouch in soapy water after each patient, by hand or in a washing machine (delicate cycle 30-40°C).

8.3. After-sales service

Maintenance is carried out in our workshop, as rapidly as possible. We are unable, however, to provide a unit on a loan during the repair period or to provide compensation of any sort.

In all cases, including units under guarantee, transport costs are the customer's responsibility. If the unit is examined outside the guarantee period, there will be a minimum charge for administrative and testing costs.

An estimate will be sent by mail or by fax upon receipt of the unit and completion of the diagnostic tests.

No repair can take place without a signed order from the customer.

8.4. Storage and dispatching

If the Vista is going to be stored for several days or more, remove the batteries.

The Vista is dispatched in a protective packaging. This should be kept in case it is needed at a later date.

BEWARE!

When throwing out the batteries use proper containers, following the current laws.

You must respect the current regulations concerning the destruction of the unit.

8.5. Electrical safety standards

This sign on the unit indicates to its user that complementary information is to be consulted in the accompanying documents.

The Unolter works exclusively with an internal power source and complies with standards of protection for units in class B.

The unit does not have any specific protection against humidity, so it is recommended to store it in a dry place.

CEM The Unolter conforms to the Electro-magnetic compatibility norms EN-60 601-1-2. However, if it is used in a very specific way, there can be some problems with interference.

CE Mark, according to European Directive 93/42/CEE for medical devices.

Connecting the ECG cable to the patient:

When connecting it:

Always connect the cable to the recorder first, then to the electrodes on the patient.

When removing the unit:

Always disconnect the ECG cable from the electrodes on the patient before unplugging the cable from the recorder.

NOVACOR will provide electrical circuit diagrams and information about the nature of the materials for customers if required.

8.6. Preventive maintenance

A preventive check up of the recorder is recommended every two years. This check-up will reduce the number of potential break downs and prolong its useful life. The unit will be checked for its correct functioning, in particular ECG amplifiers and safeguard battery.

The check-up must be carried out in our workshop, or by an approved distributor.

The invoicing covers the tests only, the quote for any necessary repair will be sent by mail or by fax. The repair can only be carried out upon reception of a customer order.

8.7. Physical characteristics

Length (front)	85 mm
Overall length	90 mm
Width	54 mm
Thickness	19 mm
LCD display	160 x 104 pixels
Weight batteries included	95 g
Storage temperature	- 20 °C + 45 °C
Functioning temperature	+ 10°C + 45 °C

8.8. Specifications

	Vista ; Vista Plus	Vista Access
Type of recorder	ECG holter	
Data storage (CF card)	96/128/256/512 MB	
Duration of monitoring*	6 days maxi (1 channel)	24 h maxi
(with a 128 MB CF card	3 days maxi (2 channels)	(1, 2 ou 3 channels)
supplied as standard)	2 days maxi (3 channels)	
Duration of monitoring *	11 days maxi (1 channel)	24 h maxi
(with a 512 MB CF card)	11 days maxi (2 channels)	(1, 2 ou 3 channels)
	8 days maxi (3 channels)	
Number of channels	1, 2 or 3	
Vertical resolution	10 bits	
Sampling and storing rates	200 Hz	
(no compression)		
Data capture range	12 mV (± 6 mV)	
ECG accuracy in time	± 2,5 ms	
ECG accuracy in voltage	± 6 µV	
Power supply	2 alkaline or rechargeable batteries 1,5 V AAA	

* Maximum duration is obtained with high power alkaline batteries.

8.9. Accessories

ACCESSORY
Alkaline batteries 1,5 V AAA / LR03
5 lead ECG cable 2 or 3 channels, ‘standard’ 80 cm
5 lead ECG cable 2 or 3 channels, ‘long’ 110 cm
Single size 5 lead ECG cable 2 or 3 channels for Vista Plus (100 cm)
5 lead ECG cable 2 channels « Thorax »
5 lead ECG cable 2 channels “thorax” for Vista Plus
CF Card 96 MB
CF Card 128 MB
CF Card 256 MB
CF Card 512 MB
Vista user manual
HolterSoft Ultima Manual
Protective pouch for belt or shoulder strap
« Neck » protective pouch
Belt for Vista pouch
Shoulder strap for Vista pouch

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